Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product PREVACID® (lansoprazole). PREVACID® is indicated for short-term treatment (up to 4 weeks) for healing and symptom relief of active duodenal ulcer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PREVACID® (U.S. Patent No. 4,628,098) from Hiroshi Akimoto, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 25, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PREVACID® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PREVACID® is 2,870 days. Of this time, 2,328 days occurred during the testing phase of the regulatory review period, while 542 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: July 3, 1987. FDA has verified the applicants's claim that the date that the investigational new drug application (IND) became effective was July 3, 1987.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: November 15, 1993. The applicant claims November 12, 1993, as the date the new drug application (NDA) for PREVACID® (NDA 20-406) was initially submitted. However, FDA records indicate that the applicant submitted NDA 20-406 on November 12, 1993, and FDA received the NDA on November 15, 1993, which is considered to be the NDA initially submitted date.

3. *The date the application was approved*: May 10, 1995. FDA has verified the applicant's claim that NDA 20-406 was approved on May 10, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,706 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 4, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 1, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95-31557 Filed 12-29-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95E-0303]

Determination of Regulatory Review Period for Purposes of Patent Extension; ADENOSCAN®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ADENOSCAN® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ADENOSCAN® (adenosine). ADENOSCAN® is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ADENOSCAN® (U.S. Patent No. 5,070,877) from Medco Research, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 25, 1995, FDA advised the Patent and Trademark Office that this

human drug product had undergone a regulatory review period and that the approval of ADENOSCAN® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ADENOSCAN® is 2,688 days. Of this time, 768 days occurred during the testing phase of the regulatory review period, while 1,920 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: January 9, 1988. The applicant claims December 10, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 9, 1988, which was 30 days after FDA receipt of the IND on December 10, 1987.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: February 14, 1990. The applicant claims February 9, 1990, as the date the new drug application (NDA) for ADENOSCAN® (NDA 20-059) was initially submitted. However, while FDA records indicate that the applicant submitted NDA 20-059 on February 9, 1990, FDA received the NDA on February 14, 1990, which is considered to be the date the NDA was initially submitted.

3. *The date the human drug was approved*: May 18, 1995. FDA has verified the applicant's claim that NDA-059 was approved on May 18, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 159 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 4, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 1, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95-31555 Filed 12-29-95; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Immunology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. January 22, 1996, 9:30 a.m., Gaithersburg Hilton Hotel, Salons D & E, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301-977-8900 and reference FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, 9:30 a.m. to 10:30 a.m., unless participation does not last that long; open committee discussion, 10:30 a.m. to 4 p.m. For information regarding the analyte specific reagents classification—Kaiser J. Aziz, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-3084. For information regarding the conduct of the meeting—Peter E. Maxim, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Immunology Devices Panel, code 12516.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 8, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will consider the classification of analyte specific reagents as in vitro diagnostic devices. FDA intends to develop a regulatory scheme to handle products currently being used by clinical laboratories as materials for in-house ("home brew") assays. Analyte specific reagents are chemical, poly or monoclonal antibodies, proteins, nucleic acid sequences, which, by their physio-chemical reaction with substances in a specimen, allow a test procedure to distinguish or quantify an individual chemical substance or ligand in a biological specimen. These are used in the production of in-house tests which are of high complexity under the Clinical Laboratory Improvement Act of